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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

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THE PROCTER & GAMBLE COMPANY
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,351	JANDACEK ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-78* is/are pending in the application.

4a) Of the above claim(s) *37-70 and 72-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-36 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The response filed on **4/29/09** has been entered.

2. Applicant's arguments filed 4/29/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-36 and 71 are pending in this office action. Claims 37-70 and 72-78 are withdrawn.

5. The rejection of claims 1, 3-36 and 71 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 & 3-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. (US 6,703,369) in view of Maeder et al. (US 6,730,319) for the reasons made of record in Paper No. 20081112 and as follows.

Applicant argues that “de Smidt teaches a pharmaceutical composition comprising glyceride with a melting point of 37°C and a lipase inhibitor" and neither de Smidt nor Maeder teaches or suggest the stiffening agent as recited in claim 1. Applicant argues that the current claims are directed to mono-functional alcohols and not polyols.

Further Applicant argues that "[t]he Examiner states that Maeder et al. discloses a pharmaceutically active compound with a melting point > and or = to 37°C and fatty acid droplets below body temperature 37°C, See Column 3, line 25. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, (see Column 3, lines 42-46). Applicants respectfully submit that it is an error to find an invention obvious where prior art references diverges from the invention at hand".

In response Applicant's assertion that de Smidt teaches a composition comprising a lipase inhibitor with fatty acid esters of polyols is found not persuasive. It should be noted that claim 1 does not exclude other formulations such as polyol because of the open ended language of "comprising". Nonetheless, de Smidt specifically teaches that the glyceride esters may be chosen from groups such as mono glyceride wherein the **fatty ester** has a melting point above the body temperature 37°C which is what is required by the claims. Applicant is arguing limitations not recited in the claims. It should also be noted that the claims are given their broadest claim interpretation and that the specification is not read into the claims. The claim recites a stiffening agent having a complete melting point of "about 37°C or greater". de Smidt teaches a composition comprising a stiffening agent wherein one glycerol moiety is a fatty acid with a melting point greater than 37°C (see abstract and col. 2, lines 43-40) which is greater than 33°C as required by the instant claim 1. Also de Smidt teaches specifically that the fatty acids moieties have twelve or more carbon atoms which include up to 24 carbon atoms as recited (see col. 3, lines 58+).

With regards to Maeder, claim 12 recites the stiffening agent is calcium stearate, while Maeder teaches the fatty acid salt may be calcium and the fatty acid may be stearic acid. Therefore the same composition is taught by Maeder that intrinsically has the same properties claimed (see col. 5, lines 16-25 and 40-45). In addition, nowhere in the office is action is it stated that Maeder teaches the ration of fatty acid to lipase inhibitor as 5:1. The exact quote from the office action is "[t]he only difference is that the prior art fails to teach the specific ratio of 5:1". However, Smidt makes it obvious for employing such a range. As taught by de Smidt, the stiffening agent may be in the range of 0.5-90% and the enzyme in the range of 1-50%. "If one takes 50% of the stiffening agent and 10% of the enzyme then the ratio is 1:5. As stated in the prior office action the determination of a ratio having the optimum index is well within the purview of the skilled artisan" (see page 6 of Paper No. 20081112). Based on the teachings from the prior art, one of ordinary skill in the art would have been motivated to formulate a composition by substituting the fatty esters of de Smidt with that of Maeder with a reasonable expectation of success in doing so because the teachings are directly related to the claim invention in that they comprise fatty acid and a lipase inhibitor wherein the inhibitors employed in the prior art is the same as Applicant's and the fatty acids are the same or can be substituted to give the same result.

Careful Consideration has been given and found not persuasive.

7. Claims 13-24 and 25-30 stand rejected under 35 U.S.C. 103(a)as being as unpatentable over de Smidt et al. (US 6,703,369) in view of Maeder et al. (US 6,730,319) for the reasons made of record in Paper No. 20081112 and as follows.

Applicant argues that the "present invention is directed to composition used for stiffening unabsorbed dietary fat…"

In response the above response is applied here as the same arguments were made with the same emphasis that de Smidt discloses a combination of fatty acid esters of polyols with a lipase inhibitor.

8. Claims 31-36 and 71 stand rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US (6,703,369) or Maeder et al. (US 6,730,319) in view of Hug et al. (US 6,358,522) and further in view of Park et al. (US 5,750,585).

Applicant argues that "[w]ith respect to Claims 31-36, there is no teaching or suggestion in de Smidt, Maeder, or Hug or Park et al. to use any sort of stiffening agent, alone, to stiffen lipophilic substances in the gastrointestinal tract. De Smidt, Maeder, and Hug or Park et al. all require a combination of lipase inhibitor and additional components to enhance the function of the lipase inhibitor or to lower the melting point of the lipase inhibitor". Applicant also argues that "Park discloses hydrogels which are described at column 3 to column 4, starting at line 50 of column 3. The hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one hydrophilic olefin monomer compound. The hydrogels of Park disclosed are not formed from an emulsification process using hydrophobic monomers".

In Response the same response concerning Smidt and Maeder is applied here as above. With regards to Applicant's assertion that Park teaches hydrogels by introducing a gas into a monomer solution comprising at least one hydrophilic olefin monomer, this recitation is not included in the claims. Claim 71 recites non-digestible, non-absorbable, open-celled polymeric foam. Park teaches an open-celled foam compositions and methods of orally administering said form compositions for the treatment of obesity (see column 3, lines 15-25 and column 15, lines 16-32). Claim 71 does not recite how the non-digestible, non-absorbable, open-celled polymeric foam are formed. Again Applicant is reading limitations not set forth in the claims.

Careful Consideration has been given and found not persuasive.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
7/24/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649